IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of :

Yasuyuki SUZUKI et al. : **Mail Stop: ACCOUNTING DIVISION REFUND BRANCH**

Serial No. 10/049,821 :

Filed February 19, 2002 : Attorney Docket No. 2002_0206A

PERCUTANEOUS ABSORPTION PREPARATIONS

**REQUEST FOR REFUND**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants respectfully request a refund of $400.00 charged to Deposit Account No. 23-0975 on May 17, 2006 for three independent claims over three. The charge is incorrect.

Applicants' attorney had already paid for the three additional claims in excess of three on July 20, 2005 via check no. 69345. It can be assumed that the charge originated from a Preliminary Amendment submitted May 9, 2006 (copy enclosed). It was apparently overlooked by the PTO that only amendments were made to the six total independent claims and no new material was presented. No additional fees were needed and a refund to our account is due.

Kindly credit $400.00 to the deposit account of undersigned, no. 23-0975. If there are any questions, please contact Donna Reynolds, Accounting Assistant, at (202) 721-8246.

Respectfully submitted,

Yasuyuki SUZUKI et al.

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January 9, 2007

2002_0206A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



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| In re application of | : | **Confirmation No. 2849** |
| Yasuyuki SUZUKI et al. | : | Attorney Docket No. 2002_0206A |
| Serial No. 10/049,821 | : | Group Art Unit 1616 |
| Filed February 19, 2002 | : | Examiner Alton N. Pryor |
| PERCUTANEOUS ABSORPTION PREPARATIONS | : | **Mail Stop: Amendment** |

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**AMENDMENT AND REPLY UNDER 37 C.F.R. § 1.111**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the non-final Office Action dated February 21, 2006, Applicants herein provide the following amendments and remarks.

***THE COMMISSIONER IS AUTHORIZED TO CHARGE ANY DEFICIENCY IN THE FEES FOR THIS PAPER TO DEPOSIT ACCOUNT 23-0975***

## AMENDMENTS TO THE CLAIMS

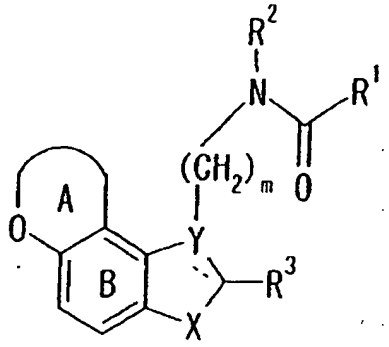
**1-6. (Cancelled)**

**7. (Previously presented)** A percutaneous absorption preparation comprising (S)-N-[2-(1,6,7,8-tetrahydro-2H-indeno [5,4-b]furan-8-yl)ethyl]acetamide, lauric diethanolamide, and optionally one or more members selected from fatty acid esters and polyhydric alcohols.

**8-19. (Cancelled)**

**20. (Previously presented)** A percutaneous absorption preparation comprising (S)-N-[2-(1,6,7,8-tetrahydro-2H-indeno[5,4-b]furan-8-yl)ethyl]acetamide, isopropyl myristate, polyethylene glycol and lauric diethanolamide.

**21. (Currently amended)** A percutaneous absorption preparation comprising a compound having a melatonin receptor agonist activity, lauric diethanolamide and optionally one or more members selected from fatty acid esters and polyhydric alcohols, wherein the compound having a melatonin receptor agonist activity is a compound represented by the formula:




wherein, $R^1$ represents ~~an optionally substituted hydrocarbon~~ a $C_{1-6}$ alkyl group;

$R^2$ represents a hydrogen atom ~~or an optionally substituted hydrocarbon group~~;

$R^3$ represents a hydrogen atom~~, an optionally substituted hydrocarbon~~ or a $C_{1-6}$ alkyl group ~~or an optionally substituted heterocyclic group~~;

X represents $CHR^4$, $NR^4$ or O in which $R^4$ represents a hydrogen atom ~~or an optionally substituted hydrocarbon group~~;

Y represents C or CH;

⋯⋯ represents a single bond or a double bond;

ring A represents ~~an optionally substituted~~; a 5- membered oxygen-containing heterocyclic ring;

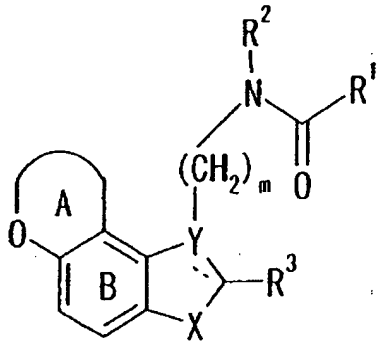
ring B represents ~~an optionally substituted~~ a benzene ring; and

m represents an integer of 1 to 4;

or a salt thereof, wherein the percutaneous absorption preparation is a skin plaster or a skin patch which is applied and/or attached to the skin.

22-32. **(Cancelled)**

33. **(Currently amended)** A percutaneous absorption preparation comprising a compound having a melatonin receptor agonist activity, lauric diethanolamide and optionally one or more members selected from fatty acid esters and polyhydric alcohols, wherein the compound having a melatonin receptor agonist activity is a compound represented by the formula:



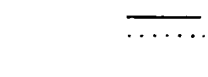
wherein, $R^1$ represents ~~an optionally substituted hydrocarbon~~ a $C_{1-6}$ alkyl group;

$R^2$ represents a hydrogen atom ~~or an optionally substituted hydrocarbon group~~;

$R^3$ represents a hydrogen atom~~, an optionally substituted hydrocarbon~~ or a $C_{1-6}$ alkyl group ~~or an optionally substituted heterocyclic group~~;

X represents $CHR^4$, $NR^4$ or O in which $R^4$ represents a hydrogen atom ~~or an optionally substituted hydrocarbon group~~;

Y represents C or CH;



represents a single bond or a double bond;

ring A represents ~~an optionally substituted~~, a 5- membered oxygen-containing heterocyclic ring;

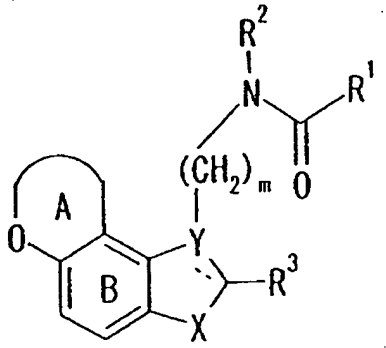
ring B represents ~~an optionally substituted~~ a benzene ring; and

m represents an integer of 1 to 4;

or a salt thereof, wherein the percutaneous absorption preparation is contained in a skin contact member comprising silicon dioxide.

**34-38. (Cancelled)**

**40. (Currently amended)** A method for percutaneous absorption of a compound having a melatonin receptor agonist activity, which comprises administering to a patient with a melatonin related disease a percutaneous absorption preparation comprising a compound having a melatonin receptor agonist activity, lauric diethanolamide and optionally one or more members selected from fatty acid esters and polyhydric alcohols, wherein the compound having a melatonin receptor agonist activity is a compound represented by the formula:




wherein, $R^1$ represents ~~an optionally substituted hydrocarbon group~~ a $C_{1-6}$ alkyl group;

$R^2$ represents a hydrogen atom ~~or an optionally substituted hydrocarbon group~~;

$R^3$ represents a hydrogen atom~~, an optionally substituted hydrocarbon group or an optionally substituted heterocyclic group~~ or a $C_{1-6}$ alkyl group;

X represents $CHR^4$, $NR^4$ or O in which $R^4$ represents a hydrogen atom ~~or an optionally substituted hydrocarbon group~~;

Y represents C or CH;

⋯⋯ represents a single bond or a double bond;

ring A represents ~~an optionally substituted,~~ a 5- membered oxygen-containing heterocyclic ring;

ring B represents ~~an optionally substituted~~ a benzene ring; and

m represents an integer of 1 to 4;

or a salt thereof.

**41. (Cancelled)**

**42. (Previously presented)** The method according to claim 39, wherein the percutaneous absorption preparation is affixed between about 6 hours before bedtime to just before bedtime.

**43. (Currently amended)** The percutaneous absorption preparation according to claim 21, wherein X represents $CHR^4$ in which $R^4$ represents a hydrogen atom ~~or an optionally substituted hydrocarbon group~~.

**44-46. (Cancelled)**

**47. (New)** The percutaneous absorption preparation according to claim 33, wherein the compound is (S)-N-[2-(1, 6, 7, 8-tetrahydro-2H-indeno-[5,4-b]furan-8-yl)ethyl]propionamide.

**48. (New)** The method of treating diseases related to melotonin according to claim 39, wherein the compound is (S)-N-[2-(1, 6, 7, 8-tetrahydro-2H-indeno-[5,4-b]furan-8-yl)ethyl]propionamide.

**49. (New)** The method of percutaneous absorption of a compound according to claim 40, wherein the compound is (S)-N-[2-(1, 6, 7, 8-tetrahydro-2H-indeno-[5,4-b]furan-8-yl)ethyl]propionamide.

## REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

## I. CLAIM STATUS & AMENDMENTS

Kindly clarify the status of the pending and rejected claims. It appears that claim 39 was omitted from the list of pending and rejected claims in items 4 and 6 on page 1 of the Office Action.

Claims 7, 20, 21, 33, 39, 40 and 42-46 were pending in this application when last examined.

Claims 21, 33, 39, 40 and 42-46 were rejected.

Claims 7 and 20 were indicated as allowed.

Claims 44-46 have been cancelled without prejudice or disclaimer thereto. Applicants reserve the right to file a continuation or divisional application on any cancelled subject matter.

Support for the amendment to $R^1$ in claims 21, 33, 39 and 40 can be found at page 30, lines 5-9.

Support for the amendment to $R^2$ in claims 21, 33, 39 and 40 can be found at page 32, lines 19-21.

Support for the amendment to $R^3$ in claims 21, 33, 39 and 40 can be found at page 34, lines 5-8.

Support for the amendment to $R^4$, ring A and ring B of claims 21, 33, 39, 40 and 43 can be found in the claims as filed.

Support for new claims 47-49 can be found at page 51, lines 15-16.

Therefore, no new matter has been added by this amendment.

Claims 7, 20, 21, 33, 39, 40, 42-43 and 47-49 are pending upon entry of this amendment.

## II. ENABLEMENT REJECTION

On pages 2-3 of the Office Action, claims 21, 33, 39, 40 and 42-46 were newly rejected under 35 U.S.C. § 112, first paragraph on the basis that the specification lacks enablement for all of the instantly claimed melatonin receptor agonists, because the heterocyclic groups in $R^3$ and the hydrocarbon carbons in $R^1$, $R^2$ and $R^3$ are overly broad.

This rejection is respectfully traversed as applied to the amended and new claims.

The test of enablement is whether one reasonably skilled in the art could make or use the invention based on the disclosure in the specification coupled with the knowledge in the art without undue experimentation. The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. The test is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See M.P.E.P. § 2164.01.

On page 3 of the Action, it was suggested that the claimed compounds be amended to compounds which are "closely related" in structure and size, polarity and electronegativity to the melatonin receptor agonist exemplified in the specification. It is respectfully submitted that the claims have been as suggested by the Examiner to compounds which are "closely related" to the compound indicated as enabled, *i.e.*, instant experimental compound A. At page 81, lines 10-12, the specification demonstrates the effectiveness of compound A.

It is respectfully submitted that this working example is representative of the compounds of the amended claims.

In addition, on pages 13-17 of the specification, numerous other compounds are disclosed with melatonin receptor agonist activity. These structures provide sufficient guidance to enable the skilled artisan to make and use other melatonin receptor agonists based on the structures in amended claims 21, 33, 39 and 40 and the new claims.

Thus, it is respectfully submitted that one of skill in the art would be able to make and use the compounds of the amended and new claims without undue experimentation given the guidance in the specification and the working example.

In view of the above, the enablement rejection of claims 21, 33, 39, 40 and 42-46 under 35 U.S.C. § 112, first paragraph, is untenable and should be withdrawn.

## CONCLUSION

In view of the foregoing amendments and remarks, the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

Yasuyuki SUZUKI et al.

By: _____

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